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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,498	03/29/2001	Eileen C. Fuchs	112701-200	5214

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EXAMINER

PRATT, HELEN F

ART UNIT	PAPER NUMBER
1761	6

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,498

Applicant(s)

FUCHS ET AL.

Examiner

Helen F. Pratt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 15, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the use of the term "macronutrient profile comprising at least vitamin E and vitamin C". Vitamins E and C are generally described as micronutrients. The specification on page 3, line 3, also uses the term "macronutrient", but the vitamins are referred to as "micronutrients on page 5, lines 16-24).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 15-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Abbruzzese et al.

Mark et al. disclose a method of administering a therapeutic composition. containing protein, in the amount of 15-20 % which can be hydrolyzed whey protein (col. 3, lines 35-55) (with 100% being from hydrolyzed whey protein as in claim 4), a lipid source which can be omega-6 to omega-3 ratio of 7:1 in the amount of 20-50% (col. 4,

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lines 34-47), vitamins and minerals which are known to include A and E (col. 4, lines 48-47-54) and a carbohydrate source such as maltodextrin, corn starch, sucrose and corn syrup (col. 4, lines 6-14). Claims 1 - 4, 6, 9-12 differ from the reference in the amount of fat which is required and in using in particularly vitamins E and C. However, no patentable distinction is seen in the use of 18% and the lower level of 20% which is disclosed by the reference at this time absent anything unobvious in a difference of 2%. Also, Abbruzzese et al. disclose a composition containing omega 3 fatty acids, which contains an antioxidant system, which includes vitamins C and E. (abstract). Therefore, it would have been obvious to use amounts a little lower than cited by the reference.

Claim 7 further requires particular amounts of monounsaturated fatty acids and polyunsaturated fatty acids and claim 8 particular amounts of saturated fatty acids.. Mark et al. disclose the use of canola oil, corn oil and soybean oil all of which contain both mono and polyunsaturated fatty acids. The particular amounts are seen as within the skill of the ordinary worker, as the beneficial effects of the oils are well known, absent any unexpected results using the particular amounts of oils. Certainly, in these oils the amount of saturated fatty acids would have been less than 30%. Therefore, it would have been obvious to use known oils in particular amounts in the claimed composition.

The limitations of claims 15-23, 26-34 have been disclosed above and are obvious for those reasons. Any variations in amounts are seen as within the skill of the ordinary worker.

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Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Ballevre et al. or Kawasaki et al. and Etzel.

Ballevre et al. disclose a protein composition containing caseinoglyco-macropptide (GMP), which can be used in a nutritional supplement (col. 12, lines 20-21, lines 40-60). Also, Kawasaki et al. disclose that it is known to use GMP's in the field of food and medical supplies (col. 5, lines 60-64). Etzel disclose that it is known to use GMP as a nutraceutical in foods and in medicine (col. 1, lines 25-35). Therefore, it would have been obvious to use GMP in other nutritional formulas for its known function of providing protein.

Claims 13, 14, 24, 25, 35, 36 are rejected under 35 U.S.C. 103(e) as being unpatentable over Mark et al. in view of Abbruzzese et al. as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Cavaliere et al.

Claim 13 further requires various kinds of prebiotic fiber. Cavaliere et al. 6,326,000 disclose a composition containing bifidobacterium and fiber such as inulin and oligosaccharides (abstract and col. 5, lines 40-55). Therefore, it would have been obvious to add prebiotics to the composition for their known function of increasing the bacteria in the intestine.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday, Wednesday and Friday from 9:30 to 6:00 and Tues and Thurs. from 4:30 to 10 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on (703) 3959. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1193.

Hp 10-8-02

  
HELEN PRATT  
PRIMARY EXAMINER